



PTO/SB/21 (09-04)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/814,399	
	Filing Date	Mar 31, 2004	
	First Named Inventor	Quay, Steven C.	
	Art Unit	1623	
Total Number of Pages in This Submission	6	Examiner Name	
	Attorney Docket Number	03-02CIP	

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to (TC)
<input checked="" type="checkbox"/> Fee Attached via Deposit Account charge	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
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<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <b>Petition to make special under 37 C.F.R. § 1.102 (d)</b>
<input type="checkbox"/> Express Abandonment Request	<input checked="" type="checkbox"/> Return Receipt Postcard	
<input checked="" type="checkbox"/> Information Disclosure Statement and foreign patent and literature documents	<input type="checkbox"/> CD, Number of CD(s) _____	
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<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	Remarks	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm Name	Nastech Pharmaceuticals Company Inc.	
Signature		
Printed name	Paul G. Lunn	
Date	January 4, 2005	Reg. No. 32,743

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.		
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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant Claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT **(\$)** 130.00

## Complete if Known

Application Number 10/814,399  
Filing Date 3/31/2004  
First Named Inventor Quay, et al.  
Examiner Name  
Art Unit 1623  
Attorney Docket No. 03-02CIP

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account  
Deposit Account Number 502769  
Deposit Account Name Natche Pharmaceutical Company Inc.

The Director is authorized to: (check all that apply)  
☒ Charge fee(s) indicated below ☐ Credit any overpayments  
☐ Charge any additional fee(s) or any underpayment of fee(s)  
☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Code	Fee (\$)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	180	2005	80	Provisional filing fee	

SUBTOTAL (1) **(\$)**

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims ☐ -20\*\*\*  
Independent Claims ☐ -3\*\*\*  
Multiple Dependent  
Extra Claims Fee from below  
Fee Paid

Large Entity	Small Entity	Fee Code	Fee (\$)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) **(\$)**

\*\*\* or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(g)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
Other fee (specify) Petition to Make Special					\$130.00

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) **(\$)** 130.00

## SUBMITTED BY

Name (Print/Type) Paul G. Lunny  
Signature *Paul G. Lunny*

Registration No. (Attorney/Agent) 32,743

## Complete (if applicable)

Telephone (425) 908-3643  
Date January 4, 2005

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	3	Attorney Docket Number	03-02CIP
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### Complete if Known

Application Number	10/814,399
Filing Date	2/26/2004
First Named Inventor	Steven C. Quay et al.
Art Unit	1623
Examiner Name	
Attorney Docket Number	03-02CIP

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code <sup>3</sup> (if known)	Issued Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 2,703,302	03-01-1955	Merck & Co, Inc.	
		US- 2,703,303	03-01-1955	Merck & Co., Inc.	
		US- 2,746,796	05-22-1956	The Pharma-Craft Corporation	
		US- 2,914,222	11-24-1959	Philip Meshberg	
		US- 3,000,793	09-19-1961	Merck & Co., Inc.	
		US- 2,951,017	08-30-1960	The Distillers Company Limited	
		US- 3,057,851	10-09-1962	Armour Pharmaceutical	
		US- 3,018,225	01-23-1962	Merck & Co., Inc.	
		US- 3,120,509	02-04-1964	Hoffmann-La Roche Inc.	
		US- 3,282,781	11-01-1966	Merck & Co., Inc.	
		US- 3,548,057	12-15-1970	Merck & Co., Inc.	
		US- 3,577,537	05-04-1971	Merck & Co., Inc.	
		US- 3,584,115	06-08-1971	Arthur I. Gebhart & Angelo T. Bonduris	
		US- 3,957,986	05-18-1978	GAF Corporation	
		US- 4,174,295	11-13-1979	Montedison S.p.A.	
		US- 4,523,341	06-25-1985	Mayo Pharmaceutical Laboratories	
		US- 4,724,231	02-09-1988	Nastech Pharmaceutical, Inc.	
		US- 5,801,161	09-01-1998	Merkus, Franciscus	
		US- 5,797,390	08-25-1998	McSoley, Thomas E.	
		US- 5,925,825	07-20-1999	Merkus, Franciscus	
		US- 6,865,421	12-16-2003	Image Therm Engineering, Inc.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>3</sup> (if known)	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	† <sup>6</sup>
		EP 0131315 A2	02-15-1984	Istituto De Angeli		
		EP 0130550 A2	06-27-1984	Intermedical GmbH		
		PCT WO 88/05868 (International Application Number PCT/US88/00793)	10-23-1986 Publication Date	Nastech Pharmaceutical Company, Inc.		
		PCT WO 88-05867 (International Application Number PCT/US88/00665)	10-23-1986 Publication Date	Nastech Pharmaceutical Company, Inc.		

Examiner Signature	/Paul Ward/ (04/24/2008)	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 3

### Complete If Known

Application Number 10/814,399  
Filing Date 03/31/2004  
First Named Inventor Steven C. Quay et al.  
Art Unit  
Examiner Name  
Attorney Docket Number 03-02US

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		RAYMOND W. MONTO, JOHN W. REBUCK, MICHAEL BRENNAN, Crystalline B <sup>12</sup> Inhalation Therapy in Pernicious Anemia, The American Journal of the Medical Sciences, 2-1953, Pages 113-119, Publisher: Division of Hematology and Department of Laboratories, The Henry Ford Hospital, Detroit, Michigan Published in: Detroit, MI, US	
		RAYMOND W. MONTO, JOHN W. REBUCK, Nasal Instillation and Inhalation of Crystalline Vitamin B <sup>12</sup> in Pernicious Anemia, A.M.A. Archives of Internal Medicine, Volume 93, 1954, From the Division of Hematology (Dr. Monto) and the Department of Laboratories (Dr. Rebeck), The Henry Ford Hospital. Pages 219-230, Detroit, MI, US.	
		RAYMOND W. MONTO, JOHN W. REBUCK, Observations on the Mechanism of Intranasal Absorption of Vitamin B <sup>12</sup> in Pernicious Anemia. Blood, Volume 10, 1955, pages 1151-1155, From the Division of Hematology (Dr. Monto) and the Department of Laboratories (Dr. Rebeck), The Henry Ford Hospital. Detroit, MI, US.	
		A. KILLANDER AND I. WERNER, Studies on Maintenance Treatment of Pernicious Anaemia, Vitamin B <sup>12</sup> and Intrinsic Factor Europaisches Symposion Hamburg, 1961, Pages 663-667, Ed. H.c. Heinrich, Enke, Stuttgart, Department of Pediatrics and Internal Medicine, Akademiska, Sjukhuset, Uppsala, Sweden	
		N.K. SHINTON AND A.K. SINGH, Vitamin B <sup>12</sup> absorption by inhalation, Chemical Abstracts, Volume 66, Number 15, Coden: Chaba8, The American Chemical Society, 4/10/1967, Page 5024, Abstract 64246(e)	
		N.K. SHINTON AND A.K. SINGH, Vitamin B <sup>12</sup> Absorption by Inhalation, Brit. J. Haemat, 1967, 13. Pages 75-79, Department of Haematology, Coventry and Warwickshire Hospital, Coventry	
		FOREST LABORATORIES, INC., Long Acting oral carrier, Chemical Abstracts, Volume 77, Year 1972, Page 263, Abstract 105623(y)	
		SALLY MATHISON, RAKESH NAGILLA, AND UDAY B. KOMPELLA, Nasal Route for Direct delivery of Solutes to the Central Nervous System: Fact or Fiction? Journal of Drug Targeting, 1998, Volume 5, No. 6, pages 415-441 Department of Pharmaceutical Science, Department of Chemistry, Auburn University, Auburn, AL US	
		ANTHONY J. CUTIE AND JOHN J. SCIARRA, Intranasal Pharmaceutical Aerosols, Aerosol Age, The International authority in Spray Packaging, Aerosol Age Magazine, 10/1982, Pages 1-4	
		R.K. CHANDRA, GLORIA HERESI, AND G. WOODFORD, Double-blind controlled crossover trial of 4% intranasal sodium cromoglycate solution in patients with seasonal allergic rhinitis, Annals of Allergy, 09/1982, Volume 49, From the Department of Pediatrics, Memorial University of Newfoundland, Janeway Child Health Center and Health Sciences Center, St. John's, Newfoundland, Canada	

Examiner Signature	/Paul Ward/ (04/24/2008)	Date Considered
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Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

 $T^2$ 

Edited by JAMES E.F. REYNOLDS, Cyanocobalamin, Martindale, The Extra Pharmacopoeia, 1982, Abstract 7853-d, and Page 1645, Cyanocobalamin Injection, 28<sup>th</sup> Edition, Published by direction of the Council of The Pharmaceutical Society of Great Britain and prepared in the Society's Department of Pharmaceutical Sciences, The Pharmaceutical Press, London, UK

CHENG DER YU, RICHARD JONES, JIM WRIGHT, AND MAIDA HENESIAN, Characterization of dose delivery and spray pattern of a metered-dose flunisolide nasal spray, Drug development and Industrial Pharmacy, 1983, 9(3), Pages 473-483, Institute of Pharmaceutical Sciences, Syntex Research, Palo Alto, CA Marcel Dekker, Inc., US

ANWAR A. HUSSAIN, YUKIHIKO ARAMAKI, Studies on the Intranasal Absorption of vitamin B<sup>12</sup> in the Rat, Final Report, 12/1984, University of Kentucky, College of Pharmacy, Lexington, KY, U.S.

Valois, Pumps for Pharmacy, Year Unknown (product brochure)

JOHN J. SIARRA, Aerosols, Chapter 92, Year Unknown, Pages 1614-1621, Arnold & Marie Schwartz Collet of Pharmacy and Health Sciences, Long Island University, Brooklyn, NY, US

T.Q. NIJST, R.A. WEVERS, H.C. SCHOONDERWALDT, O.R. HOMMES, A.F.J. DE HAAN, Vitamin B12 and folate concentrations in serum and cerebrospinal fluid of neurological patients with special reference to multiple sclerosis and dementia, *Journal of Neurology, Neurosurgery, and Psychiatry*, Year 1990; 53, Page 951-954

GARCIA-ARIETA, A.; TORRADO-SANTIAGO, S.; GOYA, L.; TORRADO, J. J. Spray-dried powders as nasal absorption enhancers of cyanocobalamin, *Biol.Pharm.Bull.*, date- 2001, Volume 24, issue- 12, Pages 1411-1416, Pharmaceutical Society of Japan

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Guidance for Industry, Nasal spray and inhalation solution, suspension, and spray drug products—chemistry, manufacturing, and controls documentation, 07/2002, Pages 1-44, Food and Drug Administration, Center for Drug Evaluation and Research, Rockville, MD.

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/Paul Ward/ (04/24/2008)	Date Considered
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